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TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.	:	10/549,385	Confirmation No.: 6082
Applicant	:	Thorsten Siess, et al.	
Filed	:	June 30, 2006	
Art Unit	:	3763	
Title:	:	INTRODUCTION DEVICE FOR INTRODUCING AN OBJECT INTO A VESSEL OF A BODY	
Examiner	:	Quynh-Nhu Hoang Vu	
Docket No.:	:	IMPEL.71975	
Customer No.	:	24201	August 14, 2008

Commissioner for Patents
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PRE-APPEAL BRIEF REQUEST FOR REVIEW

INTRODUCTION

The present invention relates to an introducer for facilitating the insertion of an intravascular device into a blood vessel. The device serves to dilate intervening tissue in order to gain full access into the interior of a vessel and then provides a passageway through which the intravascular device can be introduced. The challenge has been to limit the diameter to which the tissue is dilated in order to minimize trauma to the tissue without compromising the ability to extend an intravascular device there through.

NOTICE OF APPEAL

A Notice of Appeal from the final Office action of May 14, 2008 is being filed concurrently herewith, along with the appropriate fee.

ISSUE ON APPEAL

This appeal has one issue, namely whether the pending claims are unpatentable under 35 U.S.C. § 103(a) as obvious over Fischell et al. (EP 0 596 172 A2) in view applicant's own application, Siess et al (US 2004/0044266). More particularly, the issue boils down to whether the primary reference describes or even suggests an introducer that includes a thin sheath or channel formed **exclusively** of plastic in combination with a retractable dilator. The applicants maintain that the Examiner mischaracterizes the structure and interrelationship of the various components of the cited reference in a strained (and unreasonable) effort to find the present invention therein.

ARGUMENT

The rejected claims all require the introducer device to include a retractable dilator in combination with a channel that is readily deformable. The channel is claimed in terms of a **structure** that is readily deformable, i.e. it is claimed in terms of its composition and thickness - "formed exclusively of hard plastic" with a wall thickness of "not larger than 0.06 mm." Such limitations were selected as they necessarily render an introducer sheath having such properties to be readily deformable and effectively serve to distinguish the prior art. Moreover, it avoids any confusion that could otherwise arise in attempting to quantify the "readily deformable" function of the present invention versus a "non-kinking" function of the prior art including that of the cited reference.

In the case of the primary reference, the sheath that is described therein is a metal reinforced structure which is therefore clearly not formed "exclusively of plastic." As such, the device embraces the conventional approach wherein the sheath is configured so as to resist deformation. Not only does a reinforcement structure increase the overall diameter of the device but additionally requires the reinsertion of a dilator in order to correct any deformation that does take place before an intravascular device can be extended there through. In contrast thereto, the present invention represents a thoroughly unconventional approach in this regard as it had unexpectedly been found that the substantial axial force that was typically needed to correct any deformation of a deformation-resistant sheath was the result of the sheath's own resistance to deformation rather than the forces applied by the surrounding tissue that caused the deformation.

Accordingly, the channel element of the present invention does not require the reinsertion of a dilator in order to apply sufficient axial force to correct any deformation as the axial force generated by the insertion of the intravascular device is sufficient.

In an effort to find the claimed structure in the sheath shown and described in the primary reference, the Examiner undertakes a hypothetical disassembly of the sheath and then refers to only its outer covering as the sheath while characterizing its inner reinforcement coil as a retractable dilator. This is a wholly unreasonable characterization of the structural elements as well as an unreasonable interpretation of the teachings of the reference. Not only is the outer plastic covering said to be effectively fused to the underlying metal coil (such as by heat shrinking, hot dipping or over extrusion – page 3, lines 27-32) but its projections into the spaces between adjacent windings of the coil (Figs. 2A-3D) serve to mechanically lock the covering to the coil. Additionally, the proximal end of both the outer covering as well as the reinforcement coil are described as being "moulded" to the adaptor 30 that is situated at the proximal end of the device (page 4, lines 53-73). Clearly, such construction defies disassembly while the reference clearly teaches away from any notion of the reinforcement coil being retractable from its covering. It should also be noted that the sheath (covering plus reinforcement coil) described in the reference is for use in conjunction with a dilator (page 4, line 53) that is not shown. Characterizing the covering of a reinforced introducer sheath as the introducer sheath is no more reasonable than characterizing its reinforcement coil as a dilator when the coil reinforced sheath is to be used in conjunction with a dilator.

In straining to find the claimed structure in the cited reference, the Examiner also completely ignores the teachings of the reference which clearly teach directly away from the concept of an introducer sheath that is readily deformable. Not only is the device referred to in its very title as "non-kinking", but the reliance on the reinforcement coil to prevent the collapse of the sheath is specifically mentioned throughout the specification. The metal reinforcement coil is therefore very much part and parcel of the sheath and as such teaches away from a deformable channel, let alone one that is formed exclusively of a thin plastic.

While the secondary reference does describe a dilator with a conical tip, it again relies on a conventional rigid tubing as the conduit through which an intravascular is introduced and as such suffers from the same shortcomings that are inherent in the sheath of the primary reference.

In sum, neither reference recognizes that a readily deformable channel in combination with a retractable dilator can provide the benefit of minimizing the overall cross section while nonetheless facilitating the insertion of an intravascular device therethrough. The cited references neither suggest such an approach nor describe a structure that can reasonably be interpreted as having the claimed elements.

The Notice of Appeal filing fee of $510 and Pre-Appeal Brief filing fee of $510 are being paid by credit card with this electronic transmission. The Commissioner is hereby authorized, however, to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 06-2425.

Respectfully submitted,

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